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Fanger et al.

(10) **Patent No.: US 9,161,782 B2**
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(54) **BONE ANCHOR ASSEMBLIES AND METHODS OF MANUFACTURING AND USE THEREOF**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 79 days.

This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.**
A61B 17/70 (2006.01)
A61B 17/86 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/7034*** (2013.01); ***A61B 17/7037*** (2013.01); *A61B 17/7032* (2013.01); *A61B 17/864* (2013.01); *Y10T 29/49826* (2015.01)

(58) **Field of Classification Search**
CPC A61B 17/7032; A61B 17/7034; A61B 17/7037
USPC 606/246, 254–279
See application file for complete search history.

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Primary Examiner — Anu Ramana

(57) **ABSTRACT**

A bone anchor assembly includes a bone anchor having a proximal head and a distal shaft configured to engage bone, a receiver member for receiving a spinal fixation element to be coupled to the bone anchor, an insert positioned in the proximal end of the receiver member having a pair of spaced apart insert arms defining a recess therebetween, and a closure mechanism positionable between and engaging the insert arms to capture a spinal fixation element within the recess of the insert and fix the spinal fixation element with respect to the receiver member.

20 Claims, 6 Drawing Sheets

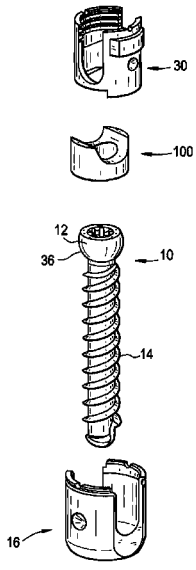

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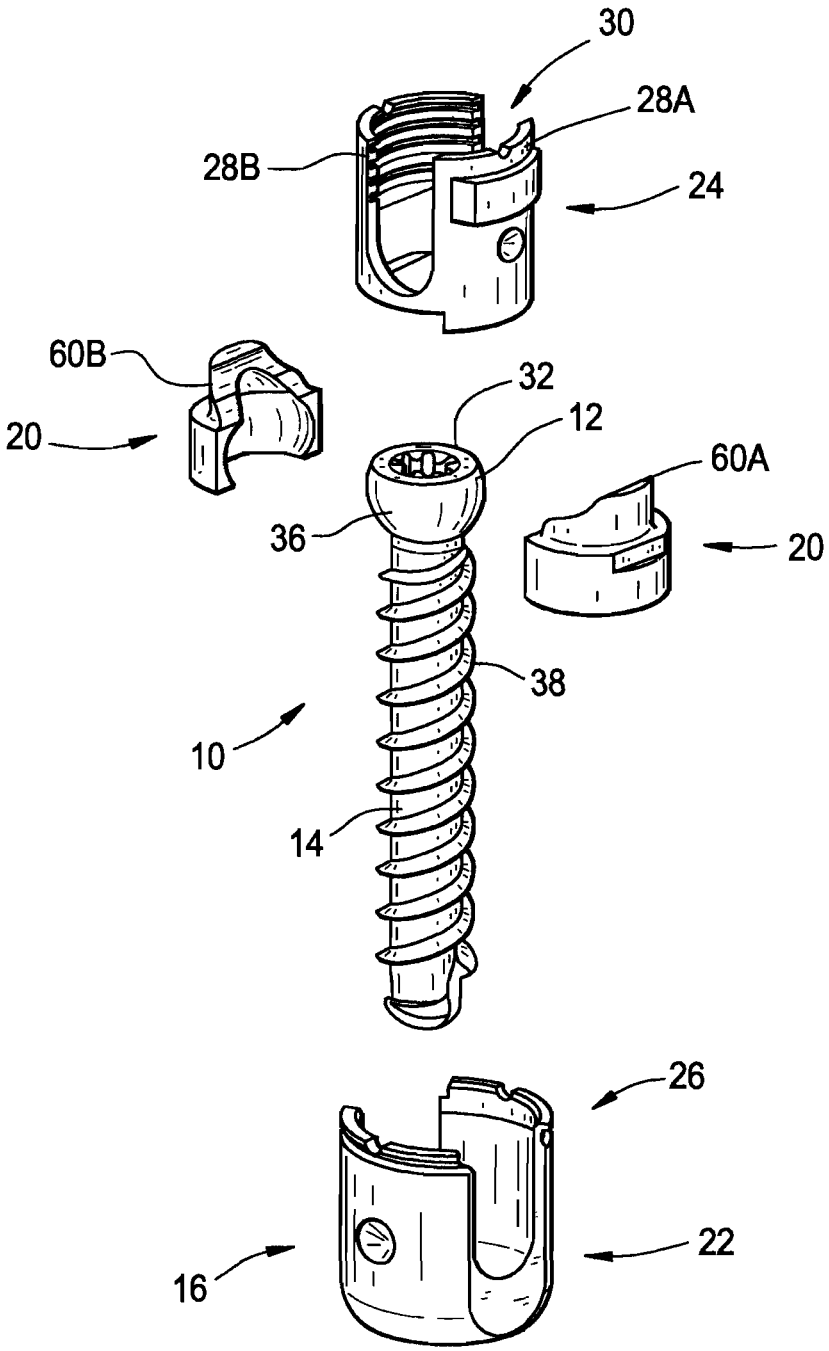
FIG. 1



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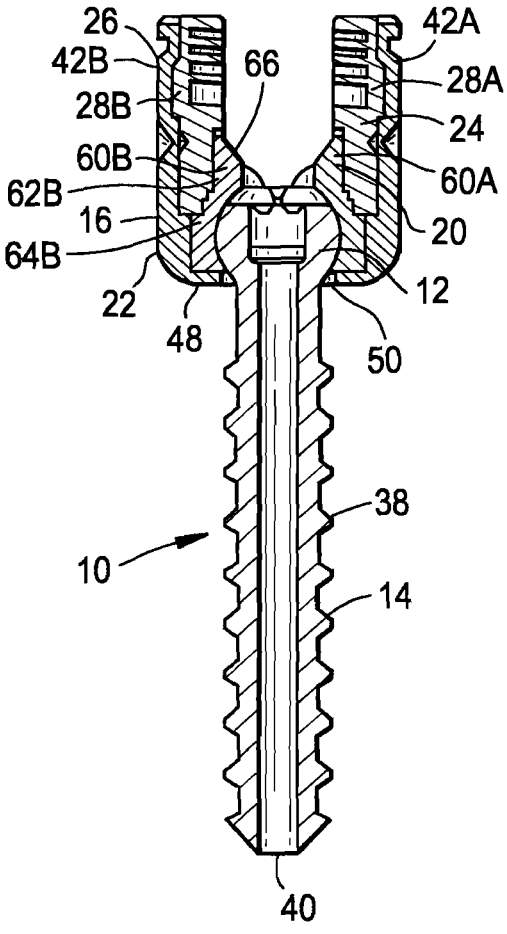
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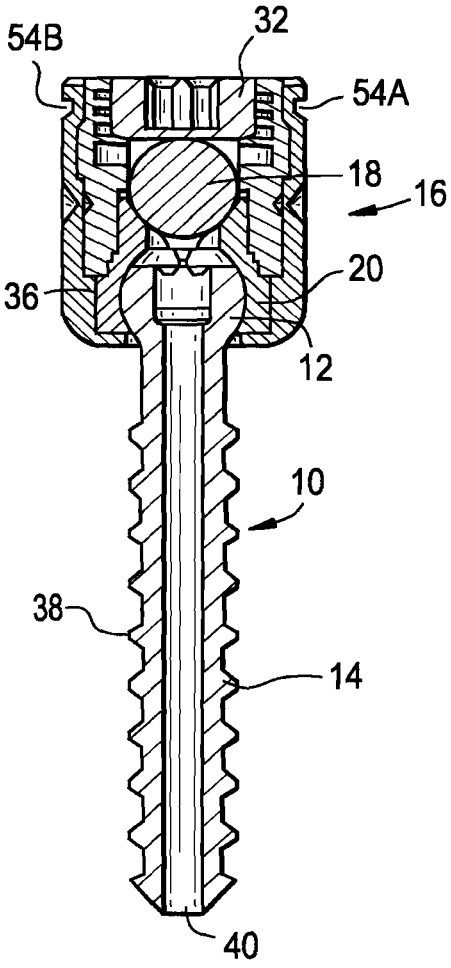
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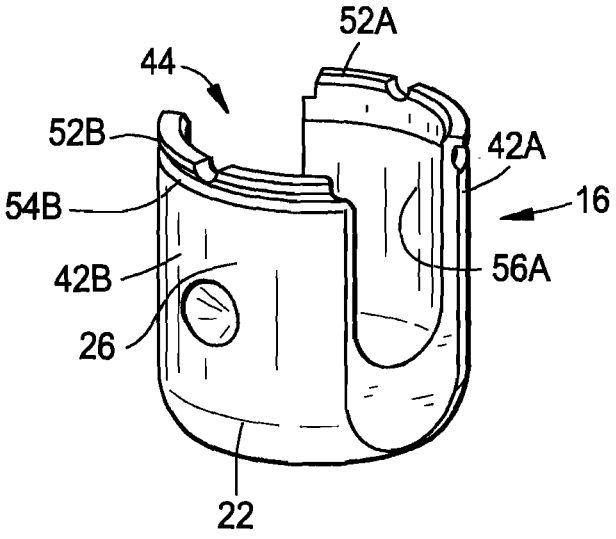
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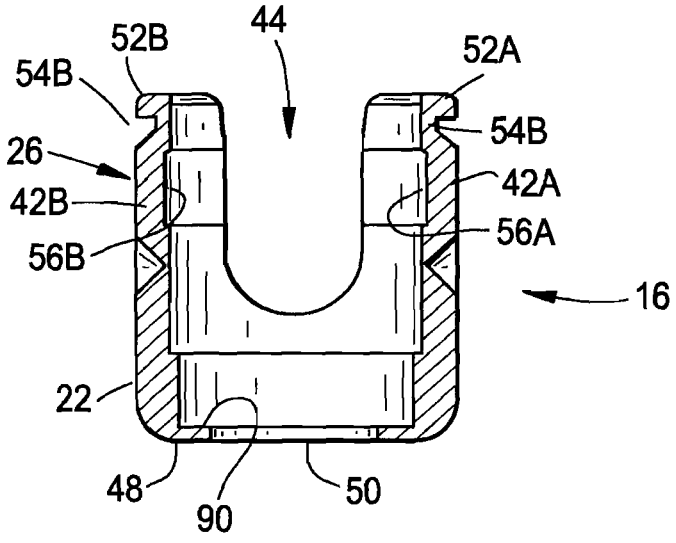
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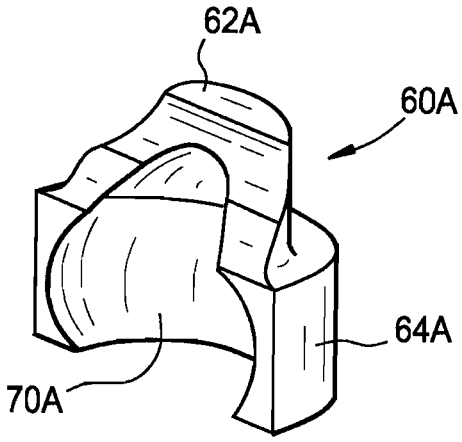

FIG. 7

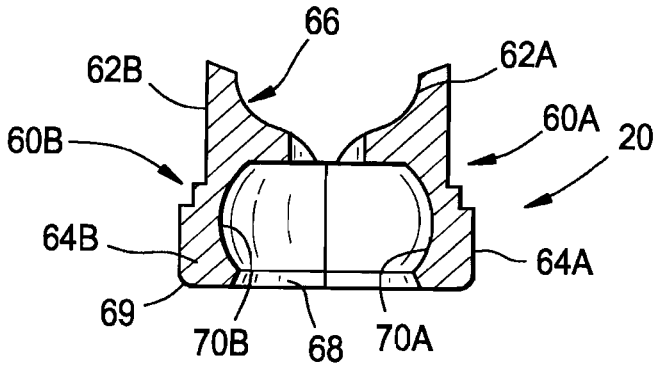

FIG. 8

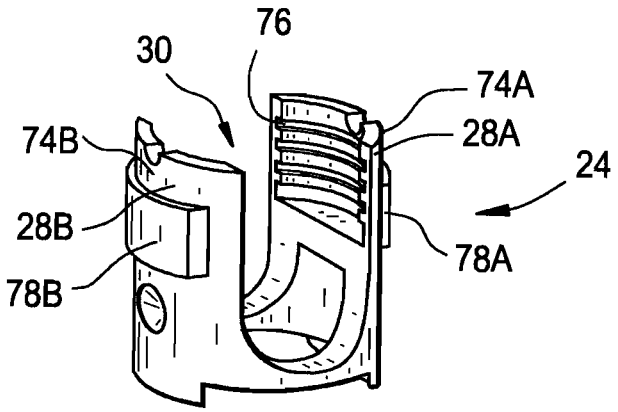
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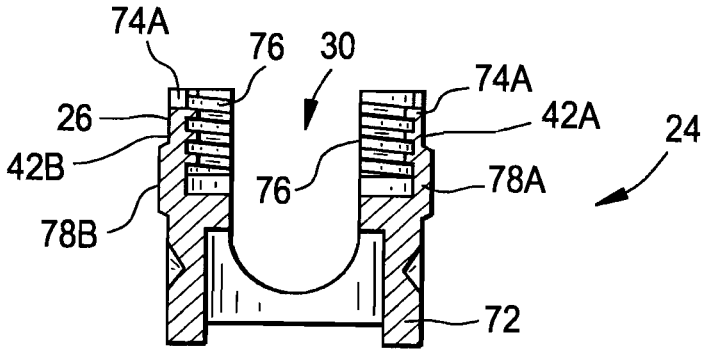
FIG. 9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78B
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FIG. 10

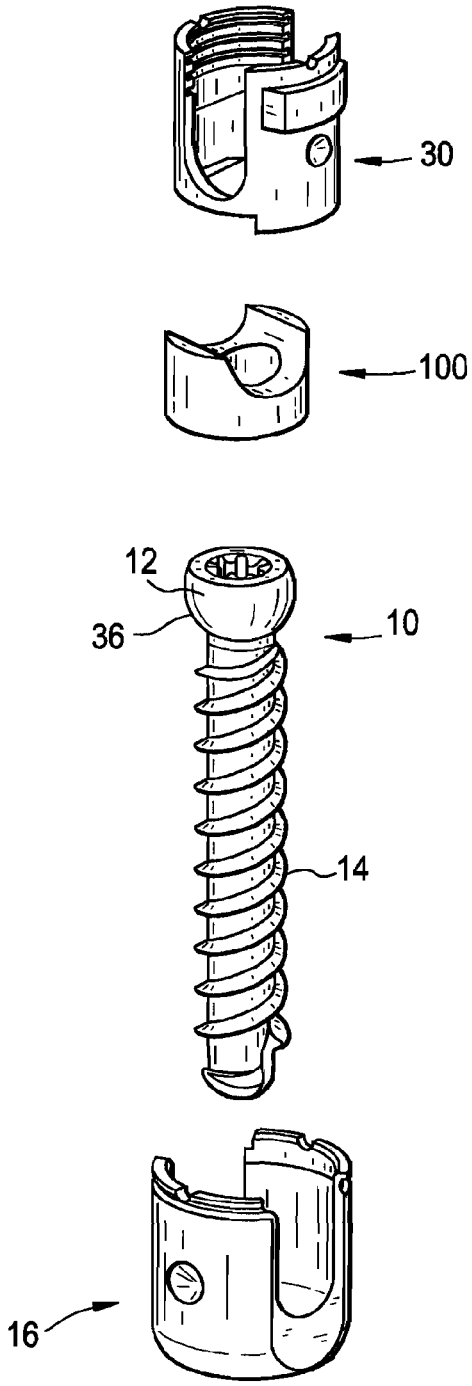
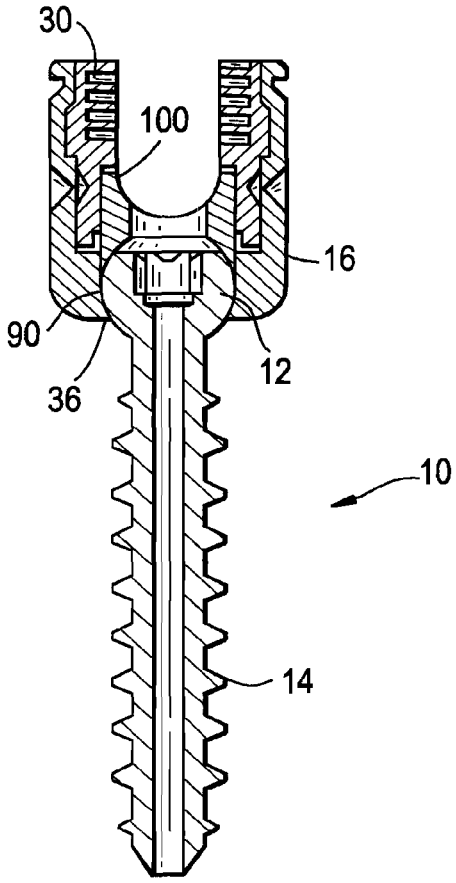


FIG. 11



BONE ANCHOR ASSEMBLIES AND METHODS OF MANUFACTURING AND USE THEREOF

CONTINUING DATA

This patent application is a continuation of U.S. Ser. No. 12/580,777, filed Oct. 16, 2009, which is incorporated by reference in its entirety.

BACKGROUND

Bone anchors may be used in orthopedic surgery to fix bone during the healing or fusion process. In spinal surgery, bone anchors may be used with spinal fixation elements, such as spinal rods, to stabilize multiple vertebrae either rigidly, in which no relative motion between the vertebrae is desired, and dynamically, in which limited, controlled motion between the vertebrae is desired.

SUMMARY

Disclosed herein are improved bone anchor assemblies and methods of manufacturing and using bone anchoring assemblies, in particular, bone anchor assemblies used in connection with spinal fixation elements to fix multiple vertebrae either rigidly or dynamically.

According to one aspect, a bone anchor assembly may comprise a bone anchor having a proximal head and a distal shaft configured to engage bone, a receiver member for receiving a spinal fixation element to be coupled to the bone anchor, a bearing positioned in the distal end of the receiver member and receiving the proximal head of the bone anchor, an insert positioned in the proximal end of the receiver member having a pair of spaced apart insert arms defining a recess therebetween, and a closure mechanism positionable between and engaging the insert arms to capture a spinal fixation element within the recess of the insert and fix the spinal fixation element with respect to the receiver member. The receiver member may have a proximal end having a pair of spaced apart arms defining a recess therebetween and a distal end having a distal end surface defining opening through which at least a portion of the bone anchor extends. At least a portion of the bearing may be interposed between the proximal head of the bone anchor and the distal end surface of the distal end of the receiver member. The insert recess may be sized and shaped to receive the spinal fixation element and each insert arm may be aligned with and positioned against an interior surface of a respective arm of the receiver member.

According to another aspect, a method of assembling a bone anchor assembly may comprise inserting a distal shank of a bone anchor through a distal opening in a distal end of a receiver member, the receiver member having a proximal end having a pair of spaced apart arms defining a recess therebetween, inserting a bearing and a proximal head of the bone anchor within the distal end of the receiver member, positioning the bearing about the proximal head of a bone anchor, positioning the bearing against a distal end surface of the distal end of the receiver member, at least a portion of the bearing being interposed between the proximal head and the distal end surface of the distal end of the receiver member, positioning an insert having a pair of opposed arms forming a U-shaped recess within the receiver member, the U-shaped recess being sized and shaped to receive a spinal fixation element, aligning each insert arm with an interior surface of a respective arm of the receiver member and the U-shaped recess of the insert with the recess in the proximal end of the receiver member, and securing the insert to the receiver member.

BRIEF DESCRIPTION OF THE FIGURES

These and other features and advantages of the devices and methods disclosed herein will be more fully understood by reference to the following detailed description in conjunction with the attached drawings in which like reference numerals refer to like elements through the different views. The drawings illustrate principles of the devices and methods disclosed herein and, although not to scale, show relative dimensions.

FIG. **1** is an exploded view of an exemplary embodiment of a bone anchor assembly,

FIG. **2** is a side view in cross section of the bone anchor assembly of FIG. **1**,

FIG. **3** is a side view in cross section of the bone anchor assembly of FIG. **1**, illustrating a spinal rod secured to the bone anchor assembly by a closure mechanism,

FIG. **4** is a perspective view of the receiver member of the bone anchor assembly of FIG. **1**,

FIG. **5** is a side view in cross section of the receiver member of FIG. **4**,

FIG. **6** is a perspective view of one component of the bearing of the bone anchor assembly of FIG. **1**,

FIG. **7** is a is a side view in cross section of the bearing components of the bone anchor assembly of FIG. **1**,

FIG. **8** is a perspective view of the insert of the bone anchor assembly of FIG. **1**,

FIG. **9** is a side view in cross section of the insert of FIG. **8**,

FIG. **10** is an exploded view of another exemplary embodiment of a bone anchor assembly, and

FIG. **11** is a side view in cross section of the bone anchor assembly of FIG. **10**.

DETAIL DESCRIPTION OF EXEMPLARY EMBODIMENTS

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

The articles "a" and "an" are used herein to refer to one or to more than one (i.e. to at least one) of the grammatical object of the article. By way of example, "an element" means one element or more than one element.

The terms "comprise," "include," and "have," and the derivatives thereof, are used herein interchangeably as comprehensive, open-ended terms. For example, use of "comprising," "including," or "having" means that whatever element is comprised, had, or included, is not the only element encompassed by the subject of the clause that contains the verb.

FIGS. **1-3** illustrate an exemplary embodiment of a bone anchor assembly including a bone anchor **10** having a proximal head **12** and a distal shaft **14** configured to engage bone, a receiver member **16** for receiving a spinal fixation element

18 to be coupled to the bone anchor 10, a bearing 20 positioned in the distal end 22 of the receiver member 16 and receiving the proximal head 12 of the bone anchor 10, an insert 24 positioned in the proximal end 26 of the receiver member 16 having a pair of spaced apart insert arms 28A, 28B defining a recess 30 therebetween, and a closure mechanism 32 positionable between and engaging the insert arms 28A, 28B to capture the spinal fixation element 18 within the recess 30 of the insert 24 and fix the spinal fixation element 18 with respect to the receiver member 16.

The proximal head 12 of the bone anchor 10 in the exemplary embodiment is generally in the shape of a truncated sphere having a planar proximal surface 32 and an approximately spherically shaped distal surface 36. The exemplary bone anchor assembly is a polyaxial bone screw. In this regards, the proximal head 12 of the bone anchor 10 engages the bearing 20 in a ball and socket like arrangement in which the proximal head 12, and thus the distal shaft 14, can pivot relative to the bearing 20 and the receiver member 16. The distal surface 36 of the bone anchor 10 and the mating surface of the bearing 20 may have any shape that facilitates this ball and socket like arrangement, including, for example, spherical (as illustrated), toroidal, conical, frustoconical, polyhedral, and any combinations of these shapes.

The distal shaft 14 of the bone anchor 10 may include bone engaging features such as one or more bone engaging threads 38. Any type or shape thread suitable for engaging bone may be employed. In the exemplary embodiment, a dual lead thread is employed. In addition, the bone anchor 10 may be cannulated, having a central lumen or cannula 40 extending the length of the bone anchor 10 to facilitate delivery of the bone anchor 10 over a guide wire in, for example, minimally invasive procedures. The distal shaft 14 may also include one or more openings or fenestrations (not shown) that communicate with the cannula 40 to permit bone in-growth or to permit the dispensing of bone cement or other materials through the bone anchor 10. The distal shaft 14 of the bone anchor 10 may also be coated with materials to permit bone growth, such as, for example, hydroxyl apatite, and the bone anchor 10 may be coated all or in-part with anti-infective materials, such as, for example, tryclosan.

Continuing to refer to FIGS. 1-3 and also referring to FIGS. 4 and 5, the proximal end 26 of the receiver member 16 of the exemplary bone anchor assembly includes a pair of spaced apart arms 42A, 42B defining a U-shaped recess 44 therebetween for receiving both the insert 24 and the spinal fixation element 18. The receiver member 16 includes a distal end 22 that is generally annular in shape and includes a distal end surface 48 defining opening 50 through which at least a portion of the bone anchor 10 extends. For example, the distal shaft 14 of the bone anchor 10 may extend through the opening 50. Each arm 42A, 42B of the proximal end 26 of the receiver member 16 extends from the distal end 22 of the receiver member 16 to a free end 52A, 52B. The outer surface of each arm 42A, 42B may include a feature, such as a recess, dimple, notch, projection, or the like, to facilitate connection of the receiver member 16 and, thus, the bone anchor assembly, to instruments. In the exemplary embodiment, for example, the outer surface of each arm 42A, 42B includes an arcuate groove 54A, 54B at the respective free end 52A, 52B of the arms. Such grooves are described in more detail in U.S. Pat. No. 7,179,261, which is incorporated herein by reference.

The interior surface of each arm 42A, 42B includes a feature, such as a recess, dimple, notch, projection, or the like, to facilitate connection of the insert 24 to the receiver member 16. In the exemplary embodiment, for example, the interior surface of each arm 42A, 42B includes a groove 56A, 56B for receiving a ridge 78A, 78B provided on the outer surface of each arm 28A, 28B of the insert 24.

The exemplary bone anchor assembly is a dynamic or mobile bone anchor assembly in which the bone anchor 10 is adjustable relative receiver member 16 after the spinal fixation element 18 is fixed relative to the receiver member 16. To facilitate the adjustability of the bone anchor 10, the bone anchor assembly includes a bearing 20 positioned within the distal end 22 of the receiver member 16 and positioned about the proximal head 12 of the bone anchor 10. Continuing to refer to FIGS. 1-3 and also referring to FIGS. 6 and 7, the bearing 20 may be a single, unitary construct or may be a multi-piece construct, for example, a two piece construct including a first bearing component 60A and a second bearing component 60B, to facilitate assembly of the bone anchor assembly. The first bearing component 60A and the second bearing component 60B cooperate to surround the proximal head 12 of the bone anchor 10 about the circumference of the proximal head 12. Each bearing component 60A, 60B includes a proximal end 62A, 62B and a distal end 64A, 64B. The proximal ends 62A, 62B of the bearing 20 cooperate to define a U-shaped seat 66 against which the spinal fixation element may be seated when the spinal fixation element 18 is fixed to the receiver member 16. Each distal end 64A, 64B of the bearing 20 is generally arcuate in shape and the distal ends 64A, 64B cooperate to define an annulus having a distal opening 68 in the distal end surface 69 of the bearing 20. When the bearing 20 is positioned within the receiver member 16 about the proximal head 12 of the bone anchor 10, the distal opening 68 of the bearing 20 is aligned with the distal opening 50 of the receiver member 16 and at least a portion of the bone anchor 10, for example, the distal shaft 14, extends through the distal opening 68 of the bearing 20 and the distal opening 50 of the receiver member 16.

Each distal end 64A, 64B of the bearing 20 has an approximately spherical shaped internal surface 70A, 70B for engaging the proximal head 12 of the bone anchor 10. The internal surfaces 70A, 70B may have a curvature that approximates the curvature of the proximal head 12 of the bone anchor 10. When the spinal fixation element 18 is fixed relative to the receiver member 16, the proximal head 12, and, thus, the bone anchor 10, can move relative to the bearing 20. To reduce wear on the bearing 20, the bearing 20 may be constructed from a wear resistant material, such as, for example, fiber reinforced polymer, such as fiber reinforced PEEK, e.g. carbon fiber reinforced PEEK. Other wear resistant materials can include UHMWPE, PEEK, polycarbonate urethane, and wear resistant ceramics and metals.

Continuing to refer to FIGS. 1-3, and FIGS. 8 and 9, the insert 24 is positioned in the proximal end 26 of the receiver member 16 and has a pair of spaced apart insert arms 28A, 28B defining a U-shaped recess 30 therebetween that is sized and shaped to receive the spinal fixation element 18. Each insert arm 28A, 28B aligned with and positioned against an interior surface of a respective arm 42A, 42B of the receiver member 16. The insert 24 of the exemplary embodiment includes a distal end 72 that is general annular in shape and has a diameter greater than the distance between the outer surfaces of the proximal end 62A, 62B of the bearing 20 such that the proximal ends 62A, 62B of the bearing 20 fit within the distal end 72 of the insert 30. Each insert arm 28A, 28B extends from the annular distal end 72 of the insert 24 to a free, proximal end 74A, 74B. Each insert arm 28A, 28B may include a feature for engaging the closure mechanism 32. In the exemplary embodiment, each insert arm 28A, 28B includes an internal thread 76 on the interior surface of the

insert arm **28**A, **28**B for engaging the closure mechanism **32**. In the exemplary embodiment, the thread **76** starts at the free, proximal end **74**A, **74**B and extends distally along at least a portion of the length of the insert arms **28**A, **28**B.

Each insert arm **28**A, **28**B includes a ridge **78**A, **78**B on an outer surface of the insert arm **28**A, **28**B. The ridges **78**A, **78**B may have a size and shape corresponding to the grooves **56**A, **56**B provide on the interior surface of the arms **42**A, **42**B of the receiver member **16**. Once assembled, the insert arms **28**A, **28**B and the insert recess **30** are aligned with the arms **42**A, **42**B and the recess **44** of the receiver member **16** and the ridges **78**A, **78**B are seated within the grooves **56**A, **56**B to prevent axial movement of the insert **24** with the receiver member **16**.

The closure mechanism **32** in the exemplary embodiment is a set screw having an external thread that engages the internal thread **76** of the insert to capture a spinal fixation element within the recess **30** of the insert **24** and, when fully tightened, to fix the spinal fixation element **18** relative to the receiver member **16**. Alternatively, the closure mechanism may be dual closure mechanism having an inner and an outer set screw, such as, for example, the Expedium Dual Innie Polyaxial Screw available from DePuy Spine, Inc. of Raynham, Mass. In addition, the closure mechanism may be a non-threaded twist in cap, such as, for example, the Monarch Typhoon Cap available from DePuy Spine, Inc. of Raynham, Mass., and described in U.S. Pat. No. 6,755,829, incorporated herein by reference.

The spinal fixation element **18** in the exemplary embodiment is a rigid spinal rod. The spinal rod may be constructed titanium, titanium alloys, stainless steel, cobalt chrome, PEEK, or other materials suitable for rigid fixation. Alternatively, the spinal fixation element **18** may be a dynamic stabilization member that allows controlled mobility between the instrumented vertebrae.

In alternative embodiments, the bone anchor assembly may be a rigid polyaxial screw in which the bone anchor **10** is fixed, rather than mobile, when the spinal fixation element **18** is fixed to the receiver member **16** of the bone anchor assembly, as illustrated in FIGS. **10-11**. In such embodiments, the bearing **20** may be eliminated and the spinal fixation element **18** may either directly contact the proximal head **12** of the bone anchor **10** or may contact an intermediate element, e.g., a compression member **100**, interposed between the spinal fixation element **18** and the proximal head **12** of the bone anchor **10** to compress the distal outer surface of the proximal head **12** into direct, fixed engagement with the distal inner surface **90** of the receiver member **16**. In such embodiments, the proximal head **12** of the bone anchor **10** engages the distal inner surface **90** in a ball and socket like arrangement in which the proximal head **12**, and thus the distal shaft **14**, can pivot relative to the receiver member **16**. The distal surface **36** of the bone anchor **10** and the distal inner surface **90** of the receiver member **16** may have any shape that facilitates this ball and socket like arrangement, including, for example, spherical (as illustrated), toroidal, conical, frustoconical, polyhedral, and any combinations of these shapes.

An exemplary method of assembling the bone anchor assembly includes inserting the distal shank **14** of the bone anchor **10** through the distal opening **50** in the distal end **22** of the receiver member **16**. The bearing **20** and the proximal head **12** of the bone anchor **10** may be positioned within the distal end **22** of the receiver member **16**. The bearing **20** may be positioned about the proximal head **12** of the bone anchor **10** prior to inserting the proximal head **12** into the receiver member **16** and, thus, the bearing **20** and the proximal head **12** are positioned collectively into the receiver member **16**. Alternatively, the proximal head **12** and the bearing **20** may be positioned separately into the receiver member **16**. If the bearing **20** is a multi-part construct, for example, a two part construct as described above, the first bearing component **60**A, and the second bearing component **60**B may be positioned about the proximal head **12** of the bone anchor **10**. Once positioned in the receiver member **16**, the distal end surface **69** of the bearing **20** may be positioned against the inner distal end surface **90** of the distal end **22** of the receiver member **16** such that at least a portion of the bearing **20** is interposed between the proximal head **20** and the inner distal end surface **90** of the distal end **22** of the receiver member **16**. In addition, the distal opening **68** of the bearing **20** is aligned with the distal opening **50** of the receiver member **16** and the distal shaft **14** of the bone anchor **10** extends through the distal opening **68** of the bearing **20** and the distal opening **50** of the receiver member **16**.

The insert **24** may be positioned within the receiver member **16**. Each insert arm **28**A, **28**B may be aligned with a respective arm **42**A, **42**B of the receiver member **16** and the U-shaped recess **30** of the insert **24** may be aligned with the recess **44** in the proximal end **26** of the receiver member **16**. The insert **24** may be secured to the receiver member **16** by positioning each of the ridges **78**A, **78**B within a respective one of the grooves **56**A, **56**B provided on the interior surface of the receiver member **16**. In one exemplary embodiment, the insert **24** may be oriented such that the insert arm **28**A, **28**B are positioned in the space between the arms **42**A, **42**B of the receiver member **16** and the insert **24** may be then rotated approximately 90° to align the insert arms **28**A, **28**B with the receiver member arms **42**A, **42**B and position the ridges **78**A, **78**B within the grooves **56**A, **56**B provided on the interior surface of the receiver member **16**.

The exemplary bone anchor assembly may be used with other bone anchor assemblies and a spinal fixation element to fix multiple vertebrae. In one exemplary method of use, the spinal fixation element **18** may be positioned within the recess **30** of the insert **24** and, thus, the recess **44** of the receiver member **16**. A closure mechanism **32** may be connected to the receiver member **16** by connecting the closure mechanism **32** to the insert **24**. For example, the closure mechanism **32** when in the form of a set screw may be rotated into engagement with the internal thread **76** provided on the arms **28**A, **28**B of the insert **24**. As the closure mechanism **32** is tightened by advancing the closure mechanism **32** distally, the closure mechanism **32** contacts the spinal fixation element **18** and advances the spinal fixation element **18** into engagement with the U-shaped seat **66** defined by the proximal ends **62**A, **62**B of the bearing **20**. The distal force provided on the spinal fixation element **18** by the closure mechanism **32** during tightening is transmitted through the bearing **20** to the receiver member **16**, and not to the proximal head **12** of the bone anchor **10**, as the bearing **20** is interposed between the proximal head **12** and the inner distal end surface **90** of the distal end **22** of the receiver member **16**. During tightening, the bearing components **60**A, **60**B may separate slightly as the spinal fixation element **18** is moved distally into the U-shaped seat **66**. The tightening of the closure mechanism **32** imparts a proximal force on the insert **24** with respect to the receiver member **16**. The interaction of the ridges **78**A, **78**B on the insert **24** within the grooves **56**A, **56**B receiver member **16** prevents separation of the insert **24** from the receiver member **16** and fixes the insert **24** relative to the receiver member **16**. Once the closure mechanism **32** is fully tightened, the spinal fixation element **18**, the insert **24**, the bearing **20**, and the receiver member **16** are fixed with respect to each other and the proximal head **12** of the bone anchor **10** remains

free to move with respect to the bearing **20**, and thus, the receiver member **16** and the spinal fixation element **18**.

While the devices and methods of the present invention have been particularly shown and described with reference to the exemplary embodiments thereof, those of ordinary skill in the art will understand that various changes may be made in the form and details herein without departing from the spirit and scope of the present invention. Those of ordinary skill in the art will recognize or be able to ascertain many equivalents to the exemplary embodiments described specifically herein by using no more than routine experimentation. Such equivalents are intended to be encompassed by the scope of the present invention and the appended claims.

What is claimed is:

1. A bone anchor assembly comprising:

a bone anchor having a proximal head and a distal shaft configured to engage bone,

a receiver member for receiving a spinal fixation element to be coupled to the bone anchor, the receiver member having

a proximal end having a pair of spaced apart arms defining a recess therebetween,

a distal end having a distal end surface defining opening through which at least a portion of the bone anchor extends,

a bearing positioned in the distal end of the receiver member and receiving the proximal head of the bone anchor, at least a portion of the bearing interposed between the proximal head of the bone anchor and the distal end surface of the distal end of the receiver member,

an insert positioned in the proximal end of the receiver member, the insert having a pair of spaced apart insert arms defining a recess therebetween, the recess being sized and shaped to receive a spinal fixation element, each insert arm aligned with and positioned against an interior surface of a respective arm of the receiver member, the insert including an annular shaped distal end, the annular shaped distal end being positioned about a portion of the bearing and engaging the bearing when the spinal fixation element is fixed to the receiver member, and

a closure mechanism positionable between and engaging the insert arms to capture a spinal fixation element within the recess of the insert and fix the spinal fixation element with respect to the receiver member.

2. The bone anchor assembly of claim **1**, wherein the proximal head of the bone anchor is in the shape of a truncated sphere having a planar proximal surface and an approximately spherically shaped distal surface.

3. The bone anchor assembly of claim **2**, wherein the bearing has a proximal end defining a U-shaped seat for receiving the spinal fixation element.

4. The bone anchor assembly of claim **3**, wherein the bearing has a distal end having a distal opening that aligns with the distal opening in the distal end of the receiver member, at least a portion of the bone anchor extending through the distal opening in the bearing and the distal opening in distal end of the receiver member.

5. The bone anchor assembly of claim **4**, wherein the distal end of the bearing surrounds the proximal head of the bone anchor.

6. The bone anchor assembly of claim **4**, wherein the distal end of the bearing has an internal surface having an approximately spherical shape.

7. The bone anchor assembly of claim **6**, wherein the internal surface of the distal end of the bearing has a curvature that approximates a curvature of the proximal head of the bone anchor.

8. The bone anchor assembly of claim **4**, wherein the bearing is a multi-piece construct.

9. The bone anchor assembly of claim **1**, wherein the bone anchor is adjustable relative to the bearing and the receiver member after the rod is fixed relative to the receiver member.

10. The bone anchor assembly of claim **1**, wherein the bearing is constructed from fiber reinforced PEEK.

11. The bone anchor assembly of claim **1**, wherein each insert arm includes an internal thread on an interior surface of the arm and the closure mechanism is a set screw.

12. The bone anchor assembly of claim **1**, wherein each insert arm includes a ridge on an outer surface of the arm, the ridge being sized and shaped to fit within a groove provided on the interior surface of the arm of the receiver member.

13. A method of assembling a bone anchor assembly, the method comprising:

inserting a distal shank of a bone anchor through a distal opening in a distal end of a receiver member, the receiver member having a proximal end having a pair of spaced apart arms defining a recess therebetween,

inserting a bearing and a proximal head of the bone anchor within the distal end of the receiver member,

positioning the bearing about the proximal head of a bone anchor,

positioning the bearing against a distal end surface of the distal end of the receiver member, at least a portion of the bearing being interposed between the proximal head and the distal end surface of the distal end of the receiver member,

positioning an insert having a pair of opposed arms forming a U-shaped recess within the receiver member with each arm of the insert positioned in a space between the spaced-apart arms of the receiver member, the U-shaped recess being sized and shaped to receive a spinal fixation element,

rotating the insert about its central longitudinal axis to align each insert arm with an interior surface of a respective arm of the receiver member and the U-shaped recess of the insert with the recess in the proximal end of the receiver member, and

securing the insert to the receiver member.

14. The method of claim **13**, wherein securing the insert to the receiver member includes positioning a ridge on an outer surface of each insert arm within a groove provided on the interior surface of the arm of the receiver member.

15. The method of claim **14**, wherein the distal end of the bearing has an internal surface having an approximately spherical shape.

16. The method of claim **13**, further comprising positioning an annular shaped distal end of the insert about a portion of the bearing.

17. The method of claim **16**, wherein annular shaped distal end of the insert is positioned about a U-shaped proximal end of the bearing, the U-shaped proximal end of the bearing forming a seat for receiving the spinal fixation element.

18. The method of claim **13**, further comprising aligning a distal opening in the distal end of the bearing with the distal opening in the distal end of the receiver member and positioning at least a portion of the bone anchor through the distal opening in the bearing and the distal opening in distal end of the receiver member.

19. The method of claim **13**, wherein positioning a bearing about a proximal head of a bone anchor includes positioning the distal end of the bearing about the proximal head of the bone anchor.

20. The method claim **13**, wherein the bearing is a two part construct and wherein positioning the bearing about the proximal head of a bone anchor includes positioning a first component of the bearing about the proximal head of the bone anchor and positioning a second component about the proximal head of the bone anchor.

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